

International Conference on Harmonization (ICH)
ESTRI EWG Meeting - Minutes
Brussels, Belgium, July 14-18, 1997 Ver 1.1

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A formal meeting of the EWG was held at Brussels. The following items were agreed for the agenda:

- 'Format' recommendations
 - ICH E2B message for EDI transmission - data attributes and relational model
 - Use of SGML DTD for E2B message
 - EDI Header Specifications for the E2B Message
- Updates to E2B SGML DTD using E2B Step 4 guideline
- Phase 2 activity report and M2 Recommendations Notebook
- Web Site issues, operations, and maintenance
- Post-ICH work plan.

Since the last Meeting the group had tested transmission of ADRs using the previous the E2B/M2 SGML DTD agreed in Narita, developed the M2 Web Site, prepared the Phase 2 report, and drafted the recommendations notebook.

The E2B Step 4 guideline was signed during the meeting and the group started to update the relational view, data attributes and the DTD of the E2B/M2 message.

It was recommended to use the M2 SGML DTD definition of the message header and the message for the electronic exchange of Individual Case Safety Reports. The message header specifies the version and release number of the message. The message defines the data elements of the Individual Case Safety Report contained in the E2B Guideline. The approved version of the DTD, initially contributed by the JPMA, will be available when finalized, for public access from the ICH Web Site (<http://www.ifpma.org/m2-main.html>).

It was recommended to use the UN/EDIFACT EDI header and trailer in the EDI transactions for the electronic exchange from data base to data base of the E2B/M2 message.

The importance of change and version control was consequently discussed and a recommendation for change management was drafted. The schedule for Implementation of the recommended standards was again discussed and it was confirmed that the EU and the FDA intend to implement the standards during 1997, and the MHW to implement during 1998. Experts from the EWG presented an update of the groups activity in Workshop V at the ICH 4 conference, this Workshop included presentations from M1 and E2B.

In its presentation to the Steering Committee the group presented a summary of future activities which included evaluation of standards for electronic transfer support of the newly approved M4 topic (The Common Technical Document). The presentation also included a proposal to set up facilities on the ICH Web Site for comment on existing Guidelines and to facilitate communication on existing ICH topics.

The FDA announced that Gary Green will be retiring from the M2 group and will be replaced by Greg Brolund who will join the group at the next meeting. It was agreed that the M2 EWG would meet again in October '97.